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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,259	10/28/2003	Jeffrey Browning	A041 CON	7052

1473 7590 02/23/2006

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/696,259		BROWNING, JEFFREY	
	Examiner		Art Unit	
	Jon Eric Angell		1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/04/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the communication filed on 11/28/2005.

Claims 1-20 are pending in the application and are addressed herein.

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-7) and the species that is SEQ ID NO: 6, in the paper filed 11/28/2005 is acknowledged.

Claims 8-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 11/28/2005.

Claims 1-7 are examined herein.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Because of the claim does not indicate that the DNA is isolated, the claim reads on a DNA found in a cell (i.e. a DNA as it is found in nature). Therefore, the claimed DNA is a product of nature and is not patentable. This rejection may be overcome by amendment of the claims to recite e.g. "an isolated DNA molecule".

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Additionally, claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial or specific asserted utility or, alternatively a well established utility.

The instant claims are drawn to DNA molecule comprising a sequence that are at least 80% homologous to SEQ ID NO: 1-3 (which encode BMOG polypeptide, SEQ ID NOS: 4-6), as well as a vector comprising the DNA molecule, a host cell comprising the vector and a process for making the polypeptide encoded by the DNA using the host cell. It is noted that claim 3 specifically encompasses variants that are at least 80% homologous to SEQ ID NOS: 1-3, but the claim does not specifically indicate that the encoded polypeptide has any particular function. As such, claim 3 encompasses sequences which encode polypeptides that do not have any particular function and can include variants which are non-functional or which have a completely different function from the polypeptides encoded by SEQ ID NOS: 1-3. It is noted that the utility of the claimed vector, host cell and method of making the polypeptide all rely on the utility of the DNA and the encoded polypeptide (BMOG).

The specification discloses that BMOG or variants thereof are expressed by germinal center B cells, and may have immunoregulatory functions or may be used to regulate the immune system in autoimmune or inflammatory disease (emphasis added, see Summary of the Invention).

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of these nucleic acids. Cited utilities identified

by the examiner include immunoregulatory functions such as regulation of the immune system in autoimmune or inflammatory disease. These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well-established utilities for the protein. No well established utilities for BMOG or variants thereof are identified in either the specification or in the cited prior art.

Given the absence of a well-established utility, the final issue is whether substantial and specific utilities are disclosed in the specification. Here, no substantial utilities that are specific to BMOG are identified.

As noted in the utility guidelines, methods of treating unspecified diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities. No substantial utility is identified for BMOG (or any BMOG variant) in the specification, only speculative utilities that lack any basis are provided. Further, none of the recited utilities in the specification are specific to BMOG polypeptide, and none rely on any unique feature of BMOG.

Finally, with regard to the utility analysis, the current situation directly tracks Examples 4 and 12 of the utility guidelines, where a protein of entirely unknown function was characterized as lacking utility. In particular, example 12 states that a receptor does not have utility since no “real world” use is identified, just as in the current situation. Further experimentation is necessary to attribute a utility to the claimed polypeptides. (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.) Thus, the present disclosure is only a starting point for further research and investigation into potential practical uses of the claimed polypeptides. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), wherein the court held:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial

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utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion.”

Claims 1-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial or specific asserted utility or, alternatively a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 3 and 4 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to DNA molecules that are at least 80% homologous with a particular disclosed sequence (SEQ ID NOS: 1-3). Claim 3 does not require that the encoded polypeptide possess any particular biological activity. Neither claim 3 nor claim 4 require that the sequence possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence homology.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making

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the claimed product, or any combination thereof. In this case, the only factor present in claim 3 is a partial structure in the form of a recitation of percent identity and claim 4 merely indicates that the encoded polypeptide has the biological activity of BMOG. It is noted that the biological activity of BMOG is not disclosed in specification. It is also respectfully pointed out that specification does not identify any particular portion of the structure that must be conserved between the variant sequences nor is there a disclosure indicating which sequences are critical for the encoded polypeptide to have the “biological activity of BMOG”. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

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One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated sequences encoding the polypeptides set forth in SEQ ID NO: 4-6 (which includes SEQ ID NOS: 1-3), but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'J.E. Angell', with a long horizontal stroke extending to the right.

J.E. Angell, Ph.D.
Patent Examiner
AU 1635